SECTION 11

510(k) Summary

K061980

Sponsor:

Siemens Medical Solutions USA, Inc.,

Ultrasound Division 1230 Shorebird Way P.O. Box 7393

Mountain View, California 94039-7393

Contact Person:

Sheila W. Pickering

Telephone:

(650) 943 7187

Fax:

(650) 943 7053

Submission Date:

July 11, 2006

Device Name:

Siemens Acuson X500 Ultrasound System

Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class:

H

Review Category: Classification Panel: Tier II Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYN Product Code 90-IYO

Diagnostic Ultrasound Transducer

FR # 892.1570

Product Code 90-ITX

A. Legally Marketed Predicate Devices

The Siemens Acuson X500 Ultrasound system is substantially equivalent to the Siemens Sonoline G60S ultrasound system.

B. Device Description:

The Siemens Acuson X500 has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Siemens Acuson X500 ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The X500 modifications are verified and validated according to the company's design control process.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG 17 2006

Sheila Pickering, Ph.D.
Senior Director of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
1230 Shorebird Way
P.O. Box 7393
MOUNTAIN VIEW CA 94039-7393

Re: K061980

Trade Name: Siemens Acuson X500™ Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 11, 2006 Received: July 17, 2006

Dear Dr. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Siemens Acuson X500TM Ultrasound System, as described in your premarket notification:



Transducer Model Number

C5-2 Convex Array C6-2 Convex Array C8-5 Convex Array

5.0C50+ Convex Array

C6-3 3D Mechanically Driven 3D Convex

Array

EV9-4 Convex Array Endovaginal

Endo-VII Mechanical Sector Endovaginal

Endo-V 3D Mechanical Sector Endovaginal

Ec9-4 Convex Array Endovaginal

BE9-4 Convex Array Endocavity

5.0L45 Linear Array

7.5L70 Linear Array

LB5-2 Linear Array

L10-5 Linear Array

VF13-5 Linear Array

VF13-5SP Linear Array

7.5L50I Linear Array

7.5L50Q Linear Array

8L3 Linear Array

C7F2 Curved Array Mechanical 3D

LAP8-4 Laparoscopic

P4-2 Phased Sector Array

5.0P10 Phased Array

MPT7-4 Phased Sector Array TEE

CW2

CW5

P9-4 Phased Sector Array

CH5-2 Convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21) CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ralph Shuping at (301) 594-1212.

Sincerely yours,

Paris h Symma for Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if

Kob 1780

known):

Device Name:

SIEMENS ACUSON X500 TM Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	of Operation			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	Р	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P	P	P	P			Note 2,3,4,5
Intraoperative (Note 6)		P	P	P		P	P			Note 3
Intraoperative Neurological		P	P	P		Р	P		BMDC	Note 2,3
Pediatric		P	P	P	P	P	P			Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P			Note 2,3,4,5
Neonatal Cephalic		P	P	P	P	P	P			Note 2,3
Adult Cephalic		P	P	P	P	P	P			Note 2
Cardiac		P	Р	P	Р	P	P			Note 2,7
Transesophageal		P	P	P	P	Р	P			Note 2,3,7
Transrectal		P	P	P		P	Р			Note 2,3,4,5
Transvaginal		P	Р	P	Ì	Р	P			Note 2,3,4,5
Transurethral						,,				, , , , ,
Intravascular										 -
Peripheral vessel		Р	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic		P	P	P		P	P		2	Note 3
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Musculo-skeletal (Superficial)		P	P	P	Р	P	P			Note 2,3,4,5
Other (specify)										, -, -, -, -, -

P = previously cleared by the FDA under # K052894) E = added under Appendix E.

Note 1	For example: breast,	testes.	thyroid.	nenis.	prostate	etc

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, and Radiological Devices K06 1 93 ()

Ensemble tissue harmonic imaging Note 2

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

For example: abdominal, vascular Note 6

Contrast agent imaging Note 7 Note 8 Virtual Format

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

K061170

known:

Device Name:

C5-2 Convex Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<u> </u>
Fetal		P	P	P		P	p		BMDC	Note 2,3,4,5,
Abdominal		P	P	P		P	P			Note 2,3,4,5,
Intraoperative Abdominal										2,5,1,6,
Intraoperative Neurological					-				<u> </u>	
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,
Small Organ										-,,,,,,,
Neonatal Cephalic									_	
Adult Cephalic										
Cardiac						•				
Trans-esophageal				•						
Transrectal										
Transvaginal							-			
Transurethral								_		
Intravascular				-						
Peripheral vessel		Р	P	P		Р	P	-	BMDC	Note 2,3,4,5,
Laparoscopic										2,000 2,0,1,0,
Musculo-skeletal (Conventional)					7				· · · · · · · · · · · · · · · · · · ·	
Musculo-skeletal (Superficial)										
Other (Specify)				İ						

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note I	For exampl	e: breast,	testes, t	hyroid,	penis,	prostate,	etc.

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

K661480

Device Name:

C6-2 Convex Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<u> </u>	
Fetal		P	P	P		P	Р		BMDC	Note 2,3,4,5,7
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7
Intraoperative (Note 6)										2,5,1,5,7
Intraoperative Neurological				-						, , ,
Pediatric		Р	Р	P		P	P		BMDC	Note 2,3,4,5,7
Small Organ (Note 1)						<u>,,,</u>				2,2,1,2,1
Neonatal Cephalic										
Adult Cephalic								*-		
Cardiac						-				
Transesophageal		Î				-		_		
Transrectal	_				Ī			· ·-		
Transvaginal										
Transurethral										
Intravascular		,								
Peripheral vessel		P	P	Р		P	Р		HWIN' I	Note 2,3,4,5,7
Laparoscopic										-1-, 1,0,1
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)			$\neg \neg$							

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note	i	For	exa	mpl	lc:	breast,	testes,	thyroid	, penis,	prostate, etc	٥.

Note 8 Virtual format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Usc (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

KU61930

known):

Device Name:

C8-5 Convex Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

		,				Mode	of Operation	1		<u> </u>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			<u> </u>							
Fetal	1		<u> </u>							
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		<u> </u>						- -		
Intraoperative Neurological	1						-			
Pediatric		Р	P	Р		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		Р	P	P		P	Р		BMDC	Note 3,4,5
Neonatal Cephalic		P	P	Р		P	P	· · · · · · · · · · · · · · · · · · ·	BMDC	Note 3,4,5
Adult Cephalic		-								7
Cardiac		Е	Е	Е		Ē	Е		BMDC	Note 3,4,5,7
Transesophageal									200	1,010 3,4,3,7
Transrectal										
Transvaginal										
Transurethral										
Intravascular]							
Peripheral vessel										
Laparoscopic									~ ~	
Musculo-skeletal (Conventional)		P	Р	P		Р	P	·	BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		E	Е	Е		Е	Е		BMDC	Note 3,4,5
Other (specify)			\Box				-			

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note I	For example:	breast,	testes, th	iyroid,	penis,	prostate,	etc.
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> Prescription Use (Per 21 CFR 801.109) (Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices, 510(k) Number.

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

For example: abdominal, vascular Note 6

Note 7 Contrast agent imaging Note 8 Virtual format

510(k) Number (if

12061980

known).

Device Name:

5.0C50+ Convex Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	Р		BMDC	Note 3,4,5
Abdominal		P	P	Р	P	P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)										11000 0, 1,0
Intraoperative Neurological				i						
Pediatric		P	Р	P	P	P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P	Р	P	Р	·	BMDC	Note 3,4,5
Neonatal Cephalic							i		Di ID C	11000 5,4,5
Adult Cephalic									· · · · ·	
Cardiac										
Transesophageal										
Transrectal						· -	, ,, <u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>			
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	Р	P	Р	P	P		BMDC	Note 3,4,5
Laparoscopic	<u> </u>						-		Dinbe	14010 3,4,3
Musculo-skeletal (Conventional)		Е	Е	E	Е	E	E		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		Е	Ē	E	E	E	E		BMDC	Note 3,4,5
Other (specify)		_	_						DNIDC	14,5

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual Format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

K661750

known):

Device Name:

C6-3 3D Mechanically Driven 3D Convex Array Transducer for use

with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic						_				
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)										······································
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)										
Neonatal Cephalic		Е	Е	Е		Е	Е		BMDC	Note 2,3,4,5
Adult Cephalic										
Cardiac							<u> </u>			
Transcsophageal							~			
Transrectal										
Transvaginal										· · · · · · · · · · · · · · · · · · ·
Transurethral							<u> </u>			
Intravascular										· · · · · · · · · · · · · · · · · · ·
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)					Ī					
Musculo-skeletal (Superficial)					1	-				
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: br	reast, testes, the	vroid penis n	rostate etc.

Note 8 Virtual format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

KOLLTEO

known):

Device Name:

EV9-4 Convex Array Endovaginal Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	-	P	P		BMDC	Note 2,3,4,5
Abdominal			Ī							,,,,-
Intraoperative (Note 6)							T -			
Intraoperative Neurological									1	
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal							-			
Transrectal		P	P	Р		Р	Р		BMDC	Note 2,3,4,5
Transvaginal		P	P	Р		P	P		BMDC	Note 2,3,4,5
Transurethral										,,,,,,
Intravascular						,				
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast,	testes,	thyroid,	penis,	prostate,	etc.
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Note 8 Virtual format

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdon

and Radiological Devices

510(k) Number ___

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

Ko61183

known):

Device Name:

Endo-VII Mechanical Sector Endovaginal Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		P	P						BM	Note 3		
Abdominal												
Intraoperative Abdominal												
Intraoperative Neurological												
Pediatric						·						
Small Organ (Note 1)												
Neonatal Cephalic		P	P						ВМ	Note 3		
Adult Cephalic												
Cardiac										, <u> </u>		
Transesophageal												
Transrectal .		Р	P		-				BM	Note 3		
Transvaginal		P	P			•			BM	Note 3		
Transurethral												
Intravascular							i					
Peripheral vessel						··				-		
Laparoscopic					7							
Musculo-skeletal Conventional												
Musculo-skeletal Superficial					1							
Other (specify)												

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast.	testes.	thyroid.	nenis	prostate et	c

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

Kobigro

known):

Device Name:

Endo-V 3D Mechanical Sector Endovaginal Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode of	Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging		Other (Specify)
Ophthalmic										
Fetal		P	P						BM	Note 3
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological				i						
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic		P	Р						ВМ	Note 3
Adult Cephalic							l			
Cardiac										
Transesophageal										
Transrectal		P	P						ВМ	Note 3
Transvaginal		P	P				l		ВМ	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)								,		
Other (specify)								·		-

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note I For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

Note 8 Virtual format

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

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510(k) Number (if

K:01750

known):

Device Name:

EC9-4 Convex Array Endovaginal Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5			
Abdominal													
Intraoperative Abdominal													
Intraoperative Neurological													
Pediatric													
Small Organ (Note 1)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac							1						
Transesophageal							,	·	Ī				
Transrectal		Р	P	Р		Р	P		BMDC	Note 2,3,4,5			
Transvaginal		P	P	P		P	Р	•	BMDC	Note 2,3,4,5			
Transurethral													
Intravascular													
Peripheral vessel													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other (specify)					ļ			•					

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Ν	ote !	l i	For	examp	l¢:	breast,	testes,	thyroi	d, pe	nis,	prostate,	etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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and Radiological Devices

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

Kob 1983

known):

Device Name:

BE9-4 Convex Array Endocavity Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	P	P		Р	P		BMDC	Note 2,3,4,5		
Abdominal												
Intraoperative Abdominal				_								
Intraoperative Neurological			l	l .								
Pediatric										-		
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac									1			
Transesophageal												
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5		
Transvaginal		P	Р	Р		P	P	·	BMDC	Note 2,3,4,5		
Transurethral												
Intravascular												
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial						-						
Other (specify)												

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off) //
Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

KO61980

known):

Device Name:

5.0L45 Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic	<u> </u>											
Fetal	<u> </u>									 		
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5		
Intraoperative (Note 6)												
Intraoperative Neurological												
Pediatric		P	P	P	P	P	Р		BMDC	Note 2,3,4,5		
Small Organ (Note 1)		P	P	P	Р	P	P		BMDC	Note 2,3,4,5		
Neonatal Cephalic							1			1,010 2,0,1,0		
Adult Cephalic												
Cardiac												
Transesophageal							- 1					
Transrectal												
Transvaginal												
Transurethral												
Intravascular				-								
Peripheral vessel		P	P	P	P	P	P	-	BMDC	Note 2,3,4,5		
Laparoscopic										2,000 2,05,1,0		
Musculo-skeletal (Conventional)		P	P	Р	P	P	P		BMDC	Note 2,3,4,5		
Musculo-skeletal (Superficial)									200	11010 2,3,4,3		
Other (specify)												

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast,	testes, thyroid.	penis, prostate, etc.

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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and Radiological Devices

510(k) Number_

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

16-61480

known):

Device Name:

7.5L70 Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic				i					<u> </u>			
Fetal												
Abdominal						-						
Intraoperative (Note 6)												
Intraoperative Neurological												
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5		
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5		
Neonatal Cephalic												
Adult Cephalic								,				
Cardiac												
Transesophageal										-		
Transrectal					i							
Transvaginal									 			
Transurethral												
Intravascular			"									
Peripheral vessel		Е	Е	Ε		Е	Е		BMDC	Note 3,4,5		
Laparoscopic						•			-			
Musculo-skeletal (Conventional)		P	P	P	Ĭ	P	Р		BMDC	Note 3,4,5		
Musculo-skeletal (Superficial)		P	P	P		P	Р			Note 3,4,5		
Other (specify)						,						

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, testes,	thyroid, pe	nis, prostate, etc.
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Note 8 Virtual format

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> > Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

KE6 1480

known):

Device Name:

LB5-2 Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System • •

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic			l									
Fetal		P	P	P		P	P		BMDC	Note 4,5		
Abdominal		P	P	P		P	P		BMDC	Note 4,5		
Intraoperative Abdominal			Ī					·—-				
Intraoperative Neurological												
Pediatric				i								
Small Organ										-		
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal								•	· · · · · · · · · · · · · · · · · · ·			
Transvaginal												
Transurethral							Ì					
Intravascular												
Peripheral vessel												
Laparoscopic										-		
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

N	ote 1	i J	or	example:	breast,	testes,	thyroid,	penis,	prostate,	etc.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging

Note 6 For example; abdominal, vascular Note 7 Contrast agent imaging

K061180

known):

Device Name:

L10-5 Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation			<u></u>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		Р	P		BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										,-,-,-
Intraoperative Neurological										
Pediatric		P	Р	P		P	Р		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		P	P	P		Р	P		BMDC	Note 2,3,4,5,8
Neonatal Cephalic		P	P	Р		Р	P		BMDC	Note 2,3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										,
Transurethral										
Intravascular								***		
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Laparoscopic)- 1 · <u>1</u> -1~
Musculo-skeletal (Conventional)		P	P	P		P	P			Note 2,3,4,5,8
Musculo-skeletal (Superficial)		Р	P	P		P	Р		PMDC	Note 2,3,4,5,8
Other (specify)					Т					

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, teste	s. thyroid.	penis, prostate.	etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SicScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

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and Radiological Devices

510(k) Number ...

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

16061980

known):

Device Name:

VF13-5 Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mod	e of Operatio	п		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal								-	1	
Abdominal										
Intraoperative (Note 6)								-		
Intraoperative Neurological							·			
Pediatric		P	Р	P	Р	P	Р		BMDC	Note 3,4,5,8
Small Organ (Note 1)		P	P	P	Р	P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	Р	P	Р	Р	P		BMDC	Note 3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal									i i i i	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	P	P	Р	P	P		BMDC	Note 3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Musculo-skeletal (Superficial)		Р	P	Р	P	P	P		BMDC	Note 3,4,5,8
Other (specify)										5,4,5,0

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note I	For example:	: breast, testes,	thyroid, peni	s, prostate, etc.

Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

1(061970

known):

Device Name:

VF13-5SP Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									1	
Fetal										
Abdominal	}									
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5,8
Intraoperative Neurological		P	P	Р		P	P		BMDC	Note 3,4,5,8
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5,8
Small Organ (Note 1)		P	Р	P		·P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	P	P		Р	P		BMDC	Note 3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal							l			
Transrectal										
Transvaginal										
Transurethral								-		
Intravascular										
Peripheral vessel		P	Р	P		P	P		BMDC	Note 3,4,5,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5,8
Musculo-skeletal Superficial		P	P	P		Р	P		BMDC	Note 3,4,5,8
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	hreast	testes	thyroid	nenis	prostate	etc
I TOLC I	i di campic.	ULCASI,	icaica,	miyioid.	Demo-	DIUSIAIC.	CIC.

Note 8 Virtual format

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Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

510(k) Number (if

KU61480

known):

Device Name:

7.5L50I Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation	Ti. :	·····	"
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										****
Pediatric									İ	
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal									i	
Transvaginal										
Transurethral								-		
Intravascular								,		
Peripheral vessel		P	Р	P		P	P		BMĎC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	Р	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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and Radiological Devices 510(k) Number

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if

16061780

known):

Device Name:

7.5L50Q Linear Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System * *

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	of Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		Р.	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological								,		
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac			I							
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular						•			1	
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)	·	P	Р	Р		Р	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example: breast,	teetes thuroid	nenie proctate etc
Note 1	roi example: bicast.	testes, inviola,	denis, brostate, etc.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 4/2

510(k) Number ...

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if

KO61980

known):

Device Name:

8L3 Linear Array Transducer for use with:

Siemens Acuson X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode	of Operation	1		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal						,				
Abdominal	Ι΄	N	N	N	N	N	N		BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	Р	P	P	Р	P		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Neonatal Cephalic										
Adult Cephalic							-			
Cardiac										
Transesophageal										
Transrectal										
Transvaginal							!			
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	Р	P		BMDC	Note 2,3,4,5,8
Musculo-skeletal (Superficial)							" - " "			
Other (specify)							<u> </u>			

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1 For example: breast, testes, thyroid, penis, p	prostate.	etc.
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

K:61980

Device Name:

C7F2 Curved array mechanical 3D transducer for use with

Siemens Acuson X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

· · · · · · · · · · · · · · · · · · ·						M	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3,4,5,7
Abdominal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Ρ	Р		Р	Ρ.		BMDC	Note 2,3,4,5,7
Small Organ										
Neonatal Cephalic					i					
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular							<u> </u>			····
Peripheral vessel		Р	Р	Р		P	Р	, 	BMDC	Note 2,3,4,5,7
Laparoscopic										
Musculo-skeletal Conventional		ρ.	Р	P		Р	Р		BMDC	Note 2,3,4,5,7
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K033196; E = added under Appendix E

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices (

51(家) Number ____

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510(k) Number (if

K061980

known):

Device Name:

LAP8-4 Laparoscopic Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal									-	
Abdominal										
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological									1	
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic									1	
Cardiac										
Transesophageal										i
Transrectal										
Transvaginal										
Transurethral									1	
Intravascular									1	
Peripheral vessel										
Laparoscopic		Р	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)								· · · · · · · · · · · · · · · · · · ·		
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

	Note 1	For example:	breast, testes,	thyroid,	penis,	prostate.	etc
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

16061980

Device Name:

P4-2 Phased Sector Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

****		•				Mode	of Operatio	n	•	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3
Cardiac	T	Р	Р	P	P	P	P		BMDC	Note 2,3,7
Transesophageal										
Transrectal						·				•
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										-
Other (specify)									1	

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1 For example: breas	t, testes, thyroid,	, penis, prostate,	etc
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Note 8 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(ki Number

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

K.61970

Device Name:

5.0P10 Phased Sector Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

**************************************		•				Mode of	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2
Abdominal		P	P	P	P	P	P		BMDC	Note 2
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2
Small Organ (Note 1)			<u> </u>			·				
Neonatal Cephalic]	P	P	P	P	P	P		BMDC	Note 2
Adult Cephalic		<u> </u>								
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal			<u> </u>							
Transvaginal	<u> </u>									
Transurethral										
Intravascular	<u> </u>	Ĺ.]						
Peripheral vessel	<u> </u>		<u> </u>	<u> </u>						
Laparoscopic										
Musculo-skeletal (Conventional)			<u> </u>							
Musculo-skeletal (Superficial)				ļ						
Other (specify)]	

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging
- Note 8 Virtual format

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

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510(k)	Number (if
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known):

K = 6 1750

Device Name:

MPT7-4 Phased Sector Array TEE Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal				-						
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		Р	P	P	P	P	P		BMDC	Note 2,3,7
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast, testes,	thyroid, pe	enis, prostate, etc.
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Prescription Use (Per 21 CFR 801.109)

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 Virtual format

510(k) Number (if known):

K.661980

Device Name:

CW2 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

			• •			Mode of	Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									Ī	
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)				İ						
Neonatal Cephalic								•		
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic						_				
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example	· breast	testes th	vroid	nenis	prostate	etc
110101	I OL CARIIIPIC	· Oroasi,	,,	i y i O i G	poins,	Di Ostate,	····

Note 2 Ensemble tissue harmonic imaging

3D imaging Note 3

B&W SieScape panoramic imaging Note 4 Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular Note 7 Contrast agent imaging

Note 8 Virtual format

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

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510(k)	Number	(if

known):

K061980

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic ·										
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic			1							
Adult Cephalic				L						
Cardiac				I						
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P			•		
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

Note 1	For example:	breast,	testes,	thyroid,	penis,	prostate, et	c.
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Prescription Use (Per 21 CFR 801.109)

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And Radiological Devices Division of Reproductive Abdominal

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Note 2 Ensemble tissue harmonic imaging

³D imaging Note 3

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Contrast agent imaging Note 7

Virtual format Note 8

510(k) Number (if known):

K061980

Device Name:

P9-4 Phased Sector Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	P	P	P	P		BMDC	Note 2		
Abdominal		P	P	P	P	P	P		BMDC	Note 2		
Intraoperative (Note 6)				l								
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2		
Pediatric		P	P	P	P	P	P		BMDC	Note 2		
Small Organ (Note 1)		P	P	P	Р	P	P					
Neonatal Cephalic		Р	Р	P	Р	P	P		BMDC	Note 2		
Adult Cephalic		P	Р	P	P	P	P					
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7		
Transesophageal												
Transrectal								-				
Transvaginal					i							
Transurethral												
Intravascular												
Peripheral vessel		P	P	P	P	₽	P		BMDC	Note 2		
Laparoscopic												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Other (specify)												

P = previously cleared by the FDA under # K050240; E = added under Appendix E.

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- Note 7 Contrast agent imaging

Note 8 Virtual format

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

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510(k) Number (if known):

K061980

Device Name:

CH5-2 Convex Array Transducer for use with:

SIEMENS ACUSON X500 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as

follows:

	Mode of Operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		P	P	P		P	Р		BMDC	Note 2,3,7,8		
Abdominal		P	P	P		P	Р		BMDC	Note 2,3,7,8		
Intraoperative (Note 6)												
Intraoperative Neurological				<u> </u>	-		,		<u> </u>			
Pediatric		P	P	P		P	P		BMDC	Note 2,3,7,8		
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	<u>.</u>								ļ			
Transrectal			<u> </u>									
Transvaginal			ļ									
Transurethral												
Intravascular												
Peripheral vessel		P	P	Р		P	Р		BMDC	Note 2,3,7,8		
Laparoscopic			<u> </u>									
Musculo-skeletal (Conventional)									<u> </u>			
Musculo-skeletal (Superficial)												
Other (specify)			L			w				<u> </u>		

P = previously cleared by the FDA under # K043016; E = added under Appendix E.

Note 1	For example:	breast,	testes,	thyroid,	penis,	prostate,	etc.
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Note 8 Virtual format

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

E 1/Viel Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging